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AUG 2 8 2012

510(k) Summary
Smith & Nephew SL-PLUS® MIA Femoral Stem with Ti/HA

Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Date of Summary:	July 26, 2012
Contact Person	John Connor, Regulatory Affairs Specialist T (901) 399-5944 F (901) 566-7961
Name of Device:	SL-PLUS® MIA Femoral Stem with Ti/HA
Common Name:	Total Hip Joint, Femoral Component, Cementless
Device Classification Name and Reference:	21 CFR 888.3353 – Hip joint metal/polymer/metal semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO, KWY, LWJ

Device Description
The SL-PLUS® MIA Femoral Stem with Ti/HA is based on the uncoated design of SL-PLUS® MIA Femoral Stem cleared via K082371. The subject stems are made from forged titanium alloy Ti-6Al-4Nb with a double coating (triple layer): titanium plasma sprayed coating (two layers) with an additional thin layer of hydroxyapatite. The Ti/HA coating is identical to the Ti/HA coating on the SL-PLUS® Standard and Lateral Femoral Stems with Ti/HA cleared via premarket notification K120211.

Intended Use
The SL PLUS® MIA Stem with and without Ti/HA is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of

its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The SL PLUS® MIA Stem with and without Ti/HA is for single use only and is intended to be implanted without bone cement.

Technological Characteristics
A review of the mechanical data indicates that the SL-PLUS® MIA Femoral Stem with Ti/HA is capable of withstanding expected *in vivo* loading without failure.

Substantial Equivalence Information
The overall design, materials, and indications for use for the SL-PLUS® MIA Femoral Stem with Ti/HA are substantially equivalent to the following commercially available predicate devices.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew Orthopaedics AG	SL-PLUS® MIA Femoral Stems	K082371	2/9/09
Smith & Nephew Orthopaedics AG	SL-PLUS® Standard and Lateral Femoral Stems with Ti/HA	K120211	7/19/12

The following tests were used as a basis for the determination of substantial equivalence:

- Stem Fatigue Testing
- Neck Fatigue Testing

All tests which are in relation to the surface characterization (physical, chemical or mechanical) are discussed in detail in the Ti/HA Coating Master File **MAF – 1762, Amendment 1** and are not included in this dossier.

Conclusion
As previously noted, this Special 510(k) Premarket Notification is being submitted to request clearance for the SL-PLUS® MIA Femoral Stem with Ti/HA. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to the commercially available predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 28 2012

Smith & Nephew, Incorporated
% Mr. John Connor
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K122296
Trade/Device Name: SL-PLUS$^{\diamond}$ MIA Femoral Stem with Ti/HA
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, KWY, LWJ
Dated: July 26, 2012
Received: July 31, 2012

Dear Mr. Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Smith & Nephew SL-PLUS° MIA Femoral Stem with Ti/HA

510(k) Number (if known): K122296

Device Name: SL-PLUS° MIA Femoral Stem with Ti/HA

Indications for Use:

The SL PLUS° MIA Stem with and without Ti/HA is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122296